IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PENNSYLVANIA EMPLOYEE BENEFIT TRUST FUND, on behalf of itself and all others similarly situated, JOSEPH MACKEN, and COMMISSIONER LINDA A. WATTERS Plaintiffs, v. ZENECA, INC. and ASTRAZENECA PHARMACEUTICALS, LP, Defendants.	Civ. No. 1:05-cv-75-ER (Lead Case)

DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF MOTION TO SEAL UNREDACTED AMENDED CONSOLIDATED CLASS ACTION COMPLAINT

Pursuant to Federal Rule of Civil Procedure 26(c), defendants AstraZeneca Pharmaceuticals, LP and Zeneca, Inc. (collectively, "AstraZeneca") hereby move for a protective order sealing the Unredacted Amended Consolidated Class Action Complaint and placing in the Court's public docket the Redacted Amended Consolidated Class Action Complaint, which has been redacted in limited part as necessary to prevent disclosure of AstraZeneca's and third parties' confidential and proprietary information.

INTRODUCTION

By agreement of the parties, on August 14, 2009, plaintiffs provisionally submitted their Amended Consolidated Class Action Complaint (the "unredacted complaint") to the Court without filing the complaint in the Court's public docket. The parties agreed to this procedure to allow AstraZeneca time to file this motion for an order placing the unredacted complaint under

seal and causing to be filed in the Court's public docket a version of the complaint that redacts competitively sensitive, confidential business information belonging to AstraZeneca and third parties (the "Confidential Information"). As explained in detail below, this information has already been ordered sealed by two other courts in related litigation. As recognized by these courts, disclosure of the Confidential Information contained in the unredacted complaint would cause significant competitive harm to AstraZeneca as well as to third parties not represented in this litigation. That harm outweighs any public interest there may be in viewing these materials, especially as protecting the Confidential Information would require only relatively minor redactions to the complaint, leaving the public fully informed of the complaint's allegations. As such, good cause exists to seal the unredacted complaint.

Good cause for this motion can also be found in the circumstances in which plaintiffs came to possess the information to be redacted. Each of the complaint's references to Confidential Information is drawn from a document that AstraZeneca or third parties produced during discovery in related litigation pending in California and Massachusetts. Each such document was produced with a prominent label "Confidential," pursuant to protective orders entered in those cases which bar plaintiffs from disseminating the document (or the information contained in it) to the public. Moreover, each of these documents has been considered by the California and Massachusetts courts upon a motion similar to this one and has been ordered to be sealed from the public record. Indeed, the complaint's passages referring to the Confidential Information are copied nearly verbatim from the plaintiffs' proffers of evidence in support of class certification in the California and Massachusetts matters, and each state court determined that the proffer should be redacted in precisely the way requested in this motion. If the unredacted complaint in this case were publicly filed, these earlier state court decisions would

effectively be undone. Thus, the strong interest in comity towards state court decisions weighs heavily in favor of this motion.

BACKGROUND

Plaintiffs allege that AstraZeneca falsely advertised and deceptively marketed its prescription drug Nexium® (esomeprazole magnesium) as superior to its drug Prilosec® (omeprazole). Plaintiffs seek relief on behalf of an alleged class of persons or entities who purchased Nexium®, including consumers, third party payors, cash payors, and those making a copayment. Plaintiffs' complaint makes the same substantive allegations as were made in cases brought under the laws of California, Massachusetts, Florida, and Arkansas.[1]

On November 28, 2005, the California court hearing similar claims involving AstraZeneca's promotion of Nexium® entered an Agreed Protective Order Regarding Confidential Information, Weiss v. AstraZeneca Pharmaceuticals LP, et al., Case No. BC 3232107 (Los Angeles County Superior Court) ("California Protective Order"). Declaration of Alycia A. Degen ("Degen Decl.") ¶ 5. On June 21, 2007, the Massachusetts court hearing related claims involving Nexium® in Commonwealth Care Alliance, et al. v. AstraZeneca Pharmaceuticals LP, et al., Civ. Act. No. 05-0269 BLS2 (Mass. Superior Court), entered a substantially similar Agreed Protective Order Regarding Confidential Information ("Massachusetts Protective Order").[2] Id. Pursuant to these Protective Orders, AstraZeneca has produced confidential and proprietary information, designated as "Confidential" in accordance

[1] The complaints were dismissed in the Florida and Arkansas cases, but not in the California or Massachusetts cases.

[2] The parties are in the process of negotiating a substantially similar protective order to govern this case, which will be filed for the Court's consideration shortly.

with Paragraph 4 of the respective Protective Orders. Id. ¶ 6. In response to subpoenas, third parties also have produced confidential and proprietary information, designated as "Confidential" pursuant to Paragraphs 4 and 9 of the California Protective Order and Paragraphs 4 and 8 of the Massachusetts Protective Order. Id. Counsel for plaintiffs in the instant case are also counsel for plaintiffs in California and Massachusetts and thus have access to AstraZeneca's confidential documents through those cases.

On October 1, 2007, plaintiffs served their motions for class certification and supporting papers in both the California and Massachusetts cases. Id. ¶ 8. In the course of briefing on plaintiffs' class certification motions, plaintiffs submitted a proffer of evidence and amended proffer of evidence, along with the documents cited in the proffers. Id. ¶¶ 8, 14. The language in the unredacted complaint that is the subject of this motion can be traced nearly verbatim to the proffers plaintiffs submitted in the California and Massachusetts cases. Id. ¶ 14, 16. Furthermore, each of the documents from which the complaint's sensitive passages are drawn was attached as an exhibit to plaintiffs' class certification papers. Id. ¶ 14-16.[3]

Both the California and Massachusetts courts have ordered that the relevant language at issue here, as well as the documents from which it was drawn, be sealed and that redacted versions be filed in their respective public dockets. Id. ¶¶ 9-12. For example, on October 18, 2007, AstraZeneca filed an unopposed motion to seal unredacted versions of the California class certification papers, including plaintiffs' proffer of evidence and the documents cited in the proffer and attached to plaintiffs' papers. AstraZeneca explained, as it does here, that the papers

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[3] A cross-reference from the unredacted complaint to the plaintiffs' class certification papers and exhibits is provided in Exhibit I to the Degen Declaration.

contained its confidential and proprietary information, as well as the proprietary information of third parties, and that serious competitive harm result from the information's disclosure. Id. ¶ 9-10. These circumstances, AstraZeneca explained, met the California standard for sealing court records, that is, there "exists an overriding interest that overcomes the right of public access to the record" and "[n]o less restrictive means exist to achieve the overriding interest." Cal. Rule of Court 2.550(d). On December 6, 2007, the California court granted the motion. Id. ¶ 11. On January 22, 2008, AstraZeneca filed a second, also unopposed motion to seal, this time related to plaintiffs' amended class certification papers, including the plaintiffs' amended proffer of evidence. On January 31, 2008, the court granted the motion. Id. ¶¶ 9-11.

In the Massachusetts case, AstraZeneca also filed an unopposed motion to impound the unredacted class certification submissions, including the plaintiffs' amended proffer of evidence and associated exhibits. AstraZeneca advanced the same reason for sealing these materials as it did before the California court and as it does in this motion: that publication of unredacted versions of these papers and documents would cause unwarranted competitive harm to AstraZeneca and unrepresented third parties, satisfying Massachusetts law's requirement of "good cause" for entry of a sealing order. See Mass. Uniform Rules on Impoundment Procedure, Rule 7. On October 29, 2008, the Massachusetts court granted the motion to seal. Id. ¶ 12.

These same issues were raised in the course of briefing on AstraZeneca's motions for summary judgment, which were filed on July 15, 2008, in California and March 18, 2009, in Massachusetts. There, plaintiffs relied upon many of the same documents and much of the same information as they had in support of their class certification motions. AstraZeneca once again raised the serious competitive concerns posed by publication of the unredacted versions of these documents in separate unopposed motions to seal. The California court granted the motion to

seal on October 24, 2008. The Massachusetts court granted the motion to seal on May 1, 2009. Id. ¶ 13. Still other orders of the state courts seal these documents and information from the public record. Id.

As this history reflects, the information reflected in unredacted complaint's sensitive portions, as well as the documents from which the information was gleaned, are currently subject to multiple orders to seal by two independent courts to have faced the same issues.

ARGUMENT

Although it is well-settled that the public has a common law right of public access to judicial records, "so also is the correlative principle that the right of access ... is not absolute." Bank of Am. Nat'l Trust & Sav. Ass'n v. Hotel Rittenhouse Assocs., 800 F.2d 339, 344 (3d Cir. 1986). "To overcome the presumption [of public access], the party seeking the protective order must show good cause by demonstrating a particular need for protection." Leucadia, Inc. v. Applied Extrusion Techs., Inc., 998 F.2d 157, 166 (3d Cir. 1993). A party demonstrates good cause by showing that the "'material is the kind of information that courts will protect'" and that "'disclosure will work a clearly defined and serious injury to the party seeking closure.'" Miller v. Ind. Hosp., 16 F.3d 549, 551 (3d Cir. 1994) (quoting Publicker Indus., Inc. v. Cohen, 733 F.2d 1059, 1071 (3d Cir. 1984)). A court must then balance "the strong common law presumption of access ... against the factors militating against access." Leucadia, 998 F.2d at 165 (internal quotation marks omitted).[4] Analyzed according to these principles, the unredacted complaint should not be filed publicly.

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[4] The public has an independent First Amendment right of access to civil trials. Publicker Indus., Inc. v. Cohen, 733 F.2d 1059, 1071 (3d Cir. 1984). However, the Third Circuit has not (continued . . .)

I. The Confidential Information In The Unredacted Complaint Is The Type Courts Will Protect And Its Disclosure Would Seriously Harm AstraZeneca and Third Parties

The Confidential Information contained in the unredacted complaint falls into one or more of four categories of protected documents, which are described in turn below.

A. Confidential FDA¶ Communications

The unredacted complaint discloses confidential communications between personnel of the United States Food and Drug Administration ("FDA") and AstraZeneca concerning Nexium®. See Compl. ¶¶ 71-72, 122. These materials include, for example, documents concerning pre-approval communications with the FDA. See Declaration of Ann Booth-Barbarin ("Booth-Barbarin Decl.") ¶ 3. FDA regulations themselves protect such information from public disclosure to facilitate a free flow of information between the FDA and drug manufacturers and to prevent competitive harm to manufacturers complying with regulatory processes. See 21 C.F.R. § 20.61(b)-(c) (exempting confidential information submitted to FDA from disclosure requirements of Freedom of Information Act); Pub. Citizen Health Research Group v. FDA, 185 F.3d 898, 903 (D.C. Cir. 1999).

(. . . continued)

applied the First Amendment right of access to documents, such as the unredacted complaint, that are filed with the court outside the context of court hearings. Regardless, for the reasons articulated in this memorandum, AstraZeneca's motion satisfies the test for sealing matters subject to the First Amendment right of access. Specifically, placing the unredacted complaint under seal serves "an important governmental interest and there is no less restrictive way to serve that governmental interest." Id. at 1070. The "protection of a party's interest in confidential commercial information," which is the basis for AstraZeneca's motion, is recognized as an important governmental interest. Id. at 1070-71. And there is no less restrictive means of protecting that interest in this case than excising from the public version of the complaint those portions that contain confidential and proprietary information.

These documents were prepared under an expectation of privacy and were expressly designated as confidential when AstraZeneca submitted them to the FDA. For example, one of the documents was submitted to the FDA with a cover expressly stating that the "[i]nformation and data submitted herein contains trade secrets, or privileged or confidential information, the property of AstraZeneca LP. Government agencies are not authorized to make it public without written permission from AstraZeneca LP." See Degen Decl. ¶ 18(1); Booth-Barbarin Decl. ¶ 3.

Such confidential FDA communications are the "kind of information that courts will protect." Miller, 16 F.3d at 551. Indeed, outside the context of statutory rights of access, the Third Circuit has protected against demands for disclosure of documents reflecting the confidential proceedings of executive agencies. North Jersey Media Group, Inc. v. Ashcroft, 308 F.3d 198, 220 (3d Cir. 2002) (finding no right of access to deportation hearings deemed to present significant national security concerns); Capital Cities Media, Inc. v. Chester, 797 F.2d 1164, 1175-76 (3d Cir. 1986) (en banc) (rejecting newspaper's contention that it was entitled to access to internal documents related to an investigation by the Pennsylvania Department of Environmental Resources).

Furthermore, disclosure of such FDA communications would work a "clearly defined and serious injury" to the integrity of FDA's pre-market review process. Disclosure of the substance of confidential communications with the FDA would chill the free flow of information that the Agency relies upon in making difficult decisions concerning drug manufacturers' applications. If these confidential communications were made public in the unredacted complaint, in the future

manufacturers and agency employees would think twice about engaging in candid discussions that could later be made public.[5]

B. Proprietary Market Research Reports

The unredacted complaint also discloses information reflecting the results of market research concerning Nexium® and other PPIs that was obtained from third-parties, including Market Measures Interactive L.P. ("MMI"). See Compl. ¶¶ 108-11; Booth-Barbarin Decl. ¶ 4; Degen Decl. 18(2). Confidential business and marketing documents of this type are commonly subject to trade secret or other confidentiality protection. Leucadia, 998 F.2d at 166 ("Documents containing trade secrets or other confidential business information may be protected from disclosure."); Bradburn Parent/Teacher Store, Inc. v. 3M, No. 02-7676, 2004 WL 1146665, at *2 (E.D. Pa. May 19, 2004) (sealing defendant's market analyses, financial projections, and strategies concerning customer relationships because disclosure of such information "taken together could clearly cause competitive harm to 3M, by giving competitors an understanding of 3M's view of the marketplace as well as 3M's competitiveness within the marketplace" and allow competitors to "anticipate 3M's responses to competition in today's marketplace"); Joint Stock Soc'y v. UDV North Am., Inc., 104 F. Supp. 2d 390, 396 (D. Del. 2000) (describing "consumer research studies, strategic plans, potential advertising and marketing campaigns or financial information" as the "type of sensitive commercial information" that federal courts have "consistently held ... is entitled to confidential protection"); Fed. R. Civ. P. 26(c)(1)(G) (authorizing courts to issue orders for good cause "requiring that a

[5] The FDA has already determined the pre-approval materials that it believes should be made public, including the Medical Review and Statistical Review which plaintiffs cite in their complaint. AstraZeneca does not seek to seal references to these publicly disclosed materials.

trade secret or other confidential research, development, or commercial information not be revealed or be revealed only in a specified way").

Disclosure of these proprietary market research studies would cause "clearly defined and serious injury" to AstraZeneca and third parties. Courts have specifically recognized that the "pharmaceutical industry is a highly competitive market where companies routinely attempt to discover a possible advantage over their competitors." Pub. Citizen Health Research Group v. Nat'l Insts. of Health, 209 F. Supp. 2d 37, 47 (D. D.C. 2002). Free access to market research for which AstraZeneca paid substantial sums would give its competitors an unfair leg up in the marketplace.

Moreover, these documents reflect confidential methodology and work product that is proprietary to the third parties. For example, the contracts between AstraZeneca its market research vendors generally prohibit AstraZeneca from disclosing the vendor's work product. Booth-Barbarin Decl. ¶ 4. Before AstraZeneca produced the MMI materials referenced in the unredacted complaint, it received MMI's permission. Degen Decl. ¶ 18(2). That permission was granted based on the understanding that the produced material would be designated as confidential, pursuant to the protective orders entered in the related litigation. Id. The reports created by MMI expressly state that they contain "Proprietary" information. Id.

Courts regularly protect from disclosure similar third-party proprietary information concerning which a party owes a duty to ensure confidentiality. See Bradburn, 2004 WL 1146665, at *2 (noting in favor of defendant's motion to seal that "3M's market share analyses [were] based upon information that 3M purchase[d] from third parties and agree[d] to keep confidential"); Mars, Inc. v. JCM Am. Corp., Civ. No. 05-3165, 2007 U.S. Dist. Lexis 9819, at *6-7 (D.N.J. February 13, 2007) (finding that plaintiff had a "legitimate private interest" in

keeping confidential trade information that it was contractually obligated to maintain in secrecy); see also Publicker, 733 F.2d at 1073-74 ("[W]here there is a binding contractual obligation not to disclose certain information which to the court seems innocuous but newsworthy; in that situation unbridled disclosure of the nature of the controversy would deprive a litigant of his right to enforce a legal obligation.").

C. Internal Strategic Documents And Customer Contact Information

The unredacted complaint includes excerpts from AstraZeneca's internal documents that plaintiffs allege reveal AstraZeneca's strategies for marketing Nexium® to consumers, physicians, and managed care organizations. See Compl. ¶¶ 90-94, 103-05, 112, 114-21, 124-32; Booth-Barbarin Decl. ¶ 5. Much of this information reflects AstraZeneca's internal processes for considering possible alternative strategies for launching and marketing Nexium®. Id. The sensitive nature of this information is conveyed in the very titles of the documents from which it is drawn, e.g., "AstraZeneca Overall US Consumer Plan" (id.. ¶ 114), "AstraZeneca PPI Consumer Marketing Plan" (id. ¶ 117), "G.I. Consumer Promotion Plan" (id. ¶ 118), and "Nexium Launch Strategy & Positioning" (id. ¶ 120). Other internal documents reflect educational materials and call notes concerning communications with physicians. Among other things, these materials reflect years of competitive intelligence about how AstraZeneca approaches sales calls, trains its salespeople, and collects, monitors, and responds to feedback from its sales force. Booth-Barbarin Decl. ¶ 5. AstraZeneca has developed this competitive intelligence at great expense and maintains its secrecy, a fact reflected by the confidentiality legends contained in many of these documents. Booth-Barbarin Decl. ¶ 5.

These materials are precisely the type that courts of this circuit have protected from public disclosure by permitting them to be filed under seal. See, e.g., Bradburn, 2004 WL

1146665, at *2 (explaining that disclosure of similar information "could likely cause serious economic harm"); Joint Stock Soc'y, 104 F. Supp. 2d at 396 (explaining that federal courts have "consistently held" that such documents are "entitled to confidential protection"). These cases reflect the common sense understanding that publication of a company's confidential strategic thinking with respect to its products and marketing — precisely the information contained in the unredacted complaint — can severely damage the company's ability to compete. Moreover, courts recognize that this competitive harm can extend well beyond the lifetime of the particular marketing campaign or product at issue in the materials: "Information related to ... internal strategies and responses to competitive pressure in the marketplace at the time [the] documents were made could in turn be used to anticipate ... responses to competition in today's marketplace." Bradburn, 2004 WL 1146665, at *2; see id. ("[T]here are no bright line rules that the Court may employ in determining whether otherwise confidential internal market analysis information is sufficiently stale to warrant public disclosure.").

D. Confidential Documents Created by Advertising Agencies

The final category of Confidential Information include references to documents concerning Nexium® that were created for AstraZeneca by advertising agencies, including Klemtner Advertising, and that Plaintiff alleges reflect AstraZeneca's strategies for marketing Nexium®. See Compl. ¶¶ 133-38; Booth-Barbarin Decl. ¶ 6. These documents reflect the same kind of analysis of potential marketing strategies discussed above with respect to AstraZeneca's internal documents. AstraZeneca expressly restricts disclosure of these sorts of materials. For example, AstraZeneca's agreements with Klemtner Advertising include stringent confidentiality provisions. Booth-Barbarin Decl. ¶ 6. Like the other confidential commercial information described above, the information gleaned from third-party advertising agency documents

warrants protection. Bradburn, 2004 WL 1146665, at *2; Joint Stock Soc'y, 104 F. Supp. 2d at 396.

II. The Potential Harm To AstraZeneca And Third Parties Outweighs The Public Interest In Redacted Portions Of The Complaint

The Court must balance the threatened harm to AstraZeneca and unrepresented third parties against the public's interest in access to those portions of the complaint containing confidential information. To aid in this balancing, the Third Circuit has articulated a non-exhaustive list of factors courts should consider:

(1) whether disclosure will violate any privacy interests;
(2) whether the information is being sought for a legitimate purpose or for an improper purpose;
(3) whether disclosure of the information will cause a party embarrassment;
(4) whether confidentiality is being sought over information important to public health and safety;
(5) whether the sharing of information among litigants will promote fairness and efficiency;
(6) whether a party benefiting from the order of confidentiality is a public entity or official; and
(7) whether the case involves issues important to the public.

Shingara v. Skiles, 420 F.3d 301, 306 (3d Cir. 2005) (quoting Glenmede Trust Co. v. Thompson, 56 F.3d 476, 483 (3d Cir. 1995)).

Consideration of these factors demonstrates that the balance of interests weighs decidedly in favor of redacting the Confidential Information from plaintiffs' complaint. With respect to the interests of the parties, disclosure of the unredacted complaint threatens to harm AstraZeneca's and unrepresented third parties' significant economic interests. Neither plaintiffs' motivation for including the confidential information in the complaint nor the potential for personal embarrassment appears implicated here. The Confidential Information does not relate to a public

health or safety concern. The complaint seeks purely economic damages; there is no dispute that Nexium® is both safe and effective as prescribed. The parties have separately negotiated for the sharing of this Confidential Information among interested litigants. Neither AstraZeneca nor the third parties whose documents and information are contained in the complaint are holders of public office or agencies of the government. Finally, the limited redactions proposed in this motion in no way impair the public's ability to understand the specifics of plaintiffs' allegations from the redacted, public complaint.

One additional factor weighs heavily in favor of AstraZeneca's motion: namely, the interest in comity towards the two state courts that have ordered that language identical to that at issue here be redacted from the publicly filed versions of pleadings before them and that the documents from which the language was drawn be filed under seal. Degen Decl. ¶¶ 14-18. Permitting the unredacted complaint in this case to be publicly filed would effectively gut the protective orders entered by the California and Massachusetts courts hearing cases brought by the same lead counsel as represent plaintiffs here. It would also undermine the delicate balance of interests reached by those courts in matters that are far more advanced than this one.

Faced with analogous circumstances, courts have expressed great reluctance to act contrary to the protective orders entered by sister courts. "Courts which have been called upon to decide discovery motions that involve requests to modify or terminate a protective order previously issued by another court, whether state or federal, have frequently felt constrained by principles of comity, courtesy, and where a federal court is asked to take such action with regard to a previously issued state court protective order, federalism." Donovan v. Lewnowski, 221 F.R.D. 587, 588 (S.D. Fla. 2004) (internal quotation marks omitted); see, e.g., Dart Indus., Inc. v. Liquid Nitrogen Process. Corp. of Cal., 50 F.R.D. 286, 292 (D. Del. 1970) (limiting discovery

"in the interest of comity" to those matters "not covered by any protective order of the Illinois District Court"); Doe v. Doe Agency, 608 F. Supp. 2d 68, 71 (D.D.C. 2009) ("When a court is confronted with an action that would involve it in a serious interference with or usurpation of [the] continuing power of another court to supervise and modify its injunctions, considerations of comity and orderly administration of justice demand that the nonrendering court should decline jurisdiction and remand the parties for their relief to the rendering court, so long as it is apparent that a remedy is available there." (internal quotation marks and alterations omitted)); cf. Camiolo v. State Farm Fire & Cas. Co., 334 F.3d 345, 357 (3d Cir. 2003) ("Principles of comity and federalism demand that a district court presented with a request to compel the disclosure of any matter occurring before a [secret state grand jury] should direct the party to first formally petition the judicial officer who possesses the supervisory authority to grant or deny such access.").

In sum, the interest in protecting AstraZeneca and unrepresented third parties from the competitive harm of publishing the confidential information contained in the unredacted complaint outweighs the public interest in access to this information. This conclusion is underscored by the fact that the information was gleaned from documents produced pursuant to protective orders issued by sister courts in related litigation that bar their public dissemination, and the fact that these courts have sealed the very language at issue here from pleadings filed in their dockets.

CONCLUSION

For the foregoing reasons, AstraZeneca respectfully requests that the Court order that the Unredacted Amended Consolidated Class Action Complaint provisionally submitted to the Court on August 14, 2009, should be filed under seal, and the Redacted Amended Consolidated Class Action Complaint should be filed in the Court's public docket.

Dated: August 21, 2009

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